

STANDARD FORMULAS

STANDARD INFANT FORMULAS

The requirements for standard infant formulas are established by the American Academy of Pediatrics Committee on Nutrition. These requirements are monitored by the Food and Drug Administration as a part of the Infant Formula Act of 1980. Through this Act, the minimum level for 29 nutrients and the maximum level for 7 nutrients are established. The label must provide a declaration of the quantitative information for each nutrient. Each manufacturer must also assure by analysis that the declared level of each essential nutrient is in each batch of formula. "In general, the concentrations of nutrients in formulas are higher than those in human milk to compensate for the possible lower bioavailability."¹

The minimum levels are defined for the following nutrients:

- Protein
- Fat
- Vitamins
 - A
 - C
 - B12
 - Pantothenic acid
 - D
 - B1 (thiamine)
 - Niacin
 - Choline
 - E
 - B2 (riboflavin)
 - Folic acid
 - Inositol
 - K
 - B6 (pyridoxine)
 - Biotin
- Minerals
 - Calcium
 - Zinc
 - Copper
 - Potassium
 - Phosphorus
 - Magnesium
 - Manganese
 - Chloride
 - Sodium
 - Selenium
 - Iron
 - Iodine

Maximum levels are defined for the following nutrients:

Protein	Fat	Vitamin A
Vitamin D	Chloride	
Sodium	Potassium	

¹ Pediatric Nutrition Handbook, 5th edition, American Academy of Pediatrics .

Milk based formulas are provided for normal infants with no feeding problems. Soy based formulas are considered to be nutritionally equivalent to milk based formulas and are widely used in the United States. Soy formulas were developed in the 1960's for infants who could not tolerate milk protein or lactose. The soy based formulas are used for infants experiencing fussiness, regurgitation, colic and/or diarrhea. Please note that colic is not always controlled with a change to a soy based formula. Some infants who maybe allergic to milk based formulas also experience difficulty with soy based formulas. These infants are switched to a protein hydrolysate formula. Issuance of standard infant formulas follows two pathways based upon the categories of contract or noncontract formula.

Contract brand formula (iron fortified) in concentrate, powder and ready to feed **does not** require a diagnosis, physician order or prior approval before issuance. The reason for issuing ready to feed formula **must** be documented in the medical record unless it is the only form of the formula which is commercially available, i.e. Alimentum. The reasons to issue ready to feed formula shall be one of the following:

1. restricted or unsanitary water supply;
2. no refrigeration; or
3. caretaker is unable to properly prepare formula.

Issuance of **noncontract** brands of formula **requires** the local agency to develop policies and procedures for review of these requests. The policies shall include:

1. If the infant is medically fragile (e.g., LBW, premature, infants released after long hospitalization, heart problems, etc.), WIC will **not** require this infant to try contract brand formula(s).
2. If the infant is not medically fragile, there must be supporting documentation concerning the contract formulas tried and the problems encountered. Use the following challenge protocol before approving the use of noncontract formula:
 - a. If requesting a noncontract iron-fortified milk based formula, then the patient must have tried and encountered problems with the contract brand iron fortified milk and soy based formulas.
 - b. If requesting a noncontract soy based formula, the patient must have tried and encountered problems with the soy based contract brand formula.
3. The following information must be on the prescription prior to changing an infant to a noncontract standard formula:
 - a. The patient's diagnosis.
 - b. Name of the formula requested.
 - c. Prescribed period of time not to exceed 12 months or one (1) year. After issuance of 4-6 months of noncontract formula, the patient's status and continued need for the formula should be assessed. This should be done during a routine nutrition education visit.

Issuance of **low iron** (noncontract) formula **requires** a diagnosis and a physician's order which contains the formula designation, length of time and the diagnosis. The diagnosis **must** be one of the following:

1. severe GI disorder
2. iron intolerance/suspected iron intolerance
3. contraindication to iron fortified formula
4. Hemosiderosis
5. Hemochromatosis
6. Sick cell anemia
7. Thalassemia